

What is claimed is:

1. A purified HMG-CoA reductase inhibitor having a purity of at least 99.7%, wherein the HMG-CoA reductase inhibitor is selected from the group consisting of pravastatin and mevastatin.

5 2. A purified HMG-CoA reductase inhibitor according to claim 1, characterized in that the selected HMG-CoA reductase inhibitor is in a lactone form or in the form of an acid or a salt.

3. A purified pravastatin having a purity of at least 99.7%.

4. A purified pravastatin sodium salt having a purity of at least 99.7%.

10 5. A purified mevastatin having a purity of at least 99.7%.

6. A purified HMG-CoA reductase inhibitor having a purity of at least 99.7% which is selected from the group consisting of pravastatin and mevastatin and which is obtained by purifying a crude HMG-CoA reductase inhibitor by means of a purification process comprising one of the steps in the process of the purification of a crude HMG-CoA reductase inhibitor which consists of displacement chromatography and involves using a displacer for displacing the HMG-CoA reductase inhibitor.

15 7. A purified HMG-CoA reductase inhibitor according to claim 6, characterized in that the selected HMG-CoA reductase inhibitor is in a lactone form or in the form of an acid or a salt.

20 8. A purified HMG-CoA reductase inhibitor according to claim 7 wherein the said HMG-CoA reductase inhibitor is pravastatin sodium salt.

9. A purified HMG-CoA reductase inhibitor according to claim 6, wherein the displacement chromatography has the following steps:

a) conditioning a chromatography column with a mobile phase;

25 feeding the HMG-CoA reductase inhibitor dissolved in the mobile phase onto the chromatography column;

introducing the displacer for displacing the HMG-CoA reductase inhibitor from the column; and

obtaining the purified HMG-CoA reductase inhibitor.

30 10. A purified HMG-CoA reductase inhibitor according to claim 9, wherein the purified HMG-CoA reductase inhibitor is obtained by collecting HMG-CoA reductase

inhibitor fractions from the stationary phase and pooling the fractions depending on the quality of purity.

11. A purified HMG-CoA reductase inhibitor according to claim 9, characterized in that the selected HMG-CoA reductase inhibitor is in a lactone form or in the form of an acid  
5 or a salt.

12. A purified HMG-CoA reductase inhibitor according to claim 9, wherein the said HMG-CoA reductase inhibitor is pravastatin sodium salt.

13. A composition of pravastatin sodium salt consisting of pravastatin sodium salt and a reduced level of at least one impurity selected from the group consisting of:

10 (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-hydroxy-1-naphthaleneheptanioic acid monosodium salt,

(aR,bR,1S,2S,6R,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-hydroxy-1-naphthaleneheptanioic acid monosodium salt,

15 (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-(3S)-3-hydroxy-1-oxobutoxy)-1-naphthaleneheptanioic acid monosodium salt,

(aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-(3R)-3-hydroxy-1-oxobutoxy)-1-naphthaleneheptanioic acid monosodium salt,

20 (aR,bR,1S,2S,6R)-1,2-dihydro-b,d,6-trihydroxy-2-methyl-1-naphthaleneheptanioic acid monosodium salt,

(aR,bR,1S,2S,6S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-1-naphthaleneheptanioic acid monosodium salt,

25 (aR,bR,1S,2S,6R,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxobutoxy)-1-naphthaleneheptanioic acid monosodium salt,

(aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxo-2-3-en-butoxy)-1-naphthaleneheptanioic acid monosodium salt,

(aR,bR,1S,2S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,3-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxobutoxy)-1-naphthaleneheptanioic acid monosodium salt,

30 (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxopentoxy)-1-naphthaleneheptanioic acid monosodium salt,

(aR,bR,1S,2S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d-dihydroxy-2-methyl-8-((2S)-2-methyl-3-hydroxy-1-oxobutoxy)-1-naphthaleneheptanioic acid monosodium salt, and  
 (aR,bR,1S,2S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d-dihydroxy-2-methyl-8-((2S)-2-methyl-4-hydroxy-1-oxobutoxy)-1-naphtalennheptanioic acid monosodium salt.

5        14. A composition of pravastatin sodium salt according to claim 13, wherein an individual impurity selected from the group consisting of:

(aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-hydroxy-1-naphthaleneheptanioic acid monosodium salt,

10      (aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-(3R)-3-hydroxy-1-oxobutoxy)-1-naphthaleneheptanioic acid monosodium salt,

(aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-1-oxopentoxy)-1-naphthaleneheptanioic acid monosodium salt,

15      (aR,bR,1S,2S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d-dihydroxy-2-methyl-8-((2S)-2-methyl-3-hydroxy-1-oxobutoxy)-1-naphthaleneheptanioic acid monosodium salt, and  
 (aR,bR,1S,2S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d-dihydroxy-2-methyl-8-((2S)-2-methyl-4-hydroxy-1-oxobutoxy)-1-naphtalennheptanioic acid monosodium salt,  
 is present in an amount of below the limit of determination.

20       15. A composition of pravastatin sodium salt according to claim 13, wherein an individual impurity selected from the group consisting of:

(aR,bR,1S,2S,6R,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-8-hydroxy-1-naphthaleneheptanioic acid monosodium salt,

(aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-Hexahydro-b,d,6-trihydroxy-2-methyl-8-((2S)-2-methyl-(3S)-3-hydroxy-1-oxobutoxy)-1-naphthaleneheptanioic acid monosodium salt, and

(aR,bR,1S,2S,6R)-1,2-dihydro-b,d,6-trihydroxy-2-methyl-1-naphthaleneheptanioic acid monosodium salt,

is present in an amount of below 0.01 % area.

25       16. A composition of pravastatin sodium salt according to claim 13, wherein an individual impurity selected from the group consisting of:

(aR,bR,1S,2S,6S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-1-

naphthaleneheptanoic acid monosodium salt,

(aR,bR,1S,2S,6R,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-  
8-((2S)-2-methyl-1-oxobutoxy)-1-naphthaleneheptanoic acid monosodium salt, and

(aR,bR,1S,2S,6S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,6-trihydroxy-2-methyl-  
5 8-((2S)-2-methyl-1-oxo-2-3-en-butoxy)-1-naphthaleneheptanoic acid monosodium salt,  
is present in an amount of below 0.1 % area.

17. A composition of pravastatin sodium salt according to claim 13, wherein the  
impurity (aR,bR,1S,2S,8S,8aR)-1,2,6,7,8,8a-hexahydro-b,d,3-trihydroxy-2-methyl-8-((2S)-  
2-methyl-1-oxobutoxy)-1-naphthaleneheptanoic acid monosodium salt is present in an  
10 amount of below 0.05 % area.